Ibis Reproductive Health

Recent evidence on the use of medication abortion with misoprostol-only

Introduction

Medication abortion accounts for more than half of all abortions in the United States. Decades of clinical evidence and experience with medication abortion use have demonstrated its safety and effectiveness. The existence of pill-based methods for induced abortion has contributed to the expansion of abortion access in important ways, including by reducing barriers to clinic-based care through telehealth provision of abortion and by expanding the cadres of providers for abortion services. Unfortunately, the Risk Evaluation and Mitigation Strategies (REMS) program that the US Food and Drug Administration (FDA) maintains for mifepristone continues to impose unnecessary and non-evidence-based restrictions that hinder the potential of mifepristone to further expand access to abortion. Recent legal threats to mifepristone, and new threats on the horizon, have the potential to further restrict access to mifepristone-based medication abortion. Existing and future barriers to mifepristone access and provision have generated widespread interest in medication abortion regimens that do not include mifepristone.

Medication abortion with misoprostol-only is a safe, highly effective, **World Health Organization-recommended** regimen for medication abortion. While commonly used around the globe, misoprostol-only regimens have rarely been offered in clinician-managed settings in the United States. This is due to early **clinical trials** which suggested that misoprostol was less effective alone than the combined regimen. More recent evidence on both **clinician** and **self-managed** use of misoprostol-only found higher effectiveness; these studies may provide insight into the potential of misoprostol-only when used in contexts where clinical follow-up care is less readily available or could pose legal risks. Given the wide availability of misoprostol at low cost, its potential for shorter time to expulsion of pregnancy, and concerns about restrictions on mifepristone in the United States, there is an urgent need to revisit the misoprostol-only regimen and its potential to expand access to abortion care options in and out of clinic settings. This brief presents recent findings on safety, effectiveness, and experiences with misoprostol-only.

The misoprostol-only medication abortion regimen

Medication abortion with misoprostol-only can be provided up to 12 weeks of pregnancy duration using **800 micrograms (µg) of misoprostol tablets administered sublingually (under the tongue), vaginally (inserted in the vagina), or buccally (between the cheek and gums), every three hours for three or four doses (2400-3200 µg total), until the pregnancy is expelled.**[1] Instruction guides on taking misoprostol-only are available **here** and **here**, and recommendations on using misoprostol-only beyond 12 weeks are available **here**.

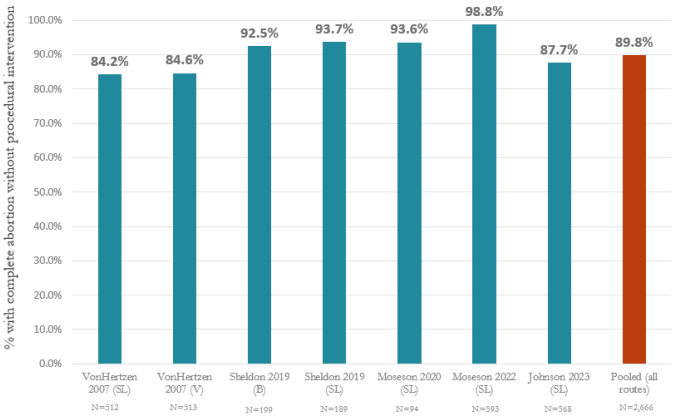
Effectiveness and safety of the endorsed misoprostol-only regimen in recent research

Abortion completion without procedural intervention using the above misoprostol-only regimen is high across recent clinical and observational studies:

- **92.5% (buccal) and 93.7% (sublingual) complete in two Latin American countries**[2]
- **98.8% complete in Argentina and Nigeria**[3]
- **100% complete in Pakistan**[4] *
- **87.7% complete in the US**[5]

Higher effectiveness between self-managed versus clinician-managed contexts may be due to the timing of follow-up, allowance for use of additional doses of misoprostol, differences in counseling and preparedness, and comfort with or access to clinical care if follow-up is needed.

Abortion completion following use of 3 doses of 800µg miso every 3 hours



*This study is not included in the chart because participants took misoprostol at a wider range of intervals (every 3-12 hours)

Among **SAFE study** participants, complications were extremely rare (<1%). Overall, 23% of participants sought medical care during or after their abortion, primarily to confirm completion of the abortion. Of these, 11% sought care for concerns related to pain, bleeding, discharge, or fever. These participants frequently reported receiving these treatments: ultrasonography, pain medications, intravenous fluids, and antibiotics.

Using misoprostol-only through pharmacy provision in the United States with Aid Access

Since 2018, **Aid Access** has offered **telemedicine medication abortion** to people across the United States through an asynchronous online platform. In June 2020, while mifepristone was temporarily unavailable, Aid Access provided prescriptions for **misoprostol** to eligible people in all 50 states. Through a qualitative study, researchers explored acceptability of misoprostol-only medication abortion acquired from an online or local pharmacy in the United States.

Among 31 participants, most described prior knowledge or doing research to learn more about misoprostol and medication abortion. Perceptions of misoprostol-only compared to the combined regimen were influenced by previous abortion experiences and a desire for a complete abortion.

> **"I just asked a lot of questions. There's a lot of research about abortion in general. [I] did a lot of research about the medication that Aid Access was able to provide me, which was misoprostol." (17yo, Maryland)**

When asked about picking up misoprostol at the pharmacy, most participants described familiarity with pharmacies, in particular their pharmacy's location, hours, and staff. This familiarity eased some of the stress associated with obtaining abortion care, although it could also raised fears about pushback or refusal by the pharmacists. Some participants preferred receiving pills by mail from an online pharmacy, which offered privacy and autonomy.

> **"I had moved to a very conservative state during COVID. And I remember just walking into CVS and thinking, are they going to give me the prescription? But the entire experience at CVS was very simplistic. I went in, I got my medication and despite sweating bullets and being so extremely nervous, everything worked out." (17yo, Virginia)**

> **"I just think it was easier for me to just have it delivered so I wouldn't have to leave the house to go to a Walgreens or CVS and get the medication…I did like, I guess, the privacy part of not having to go to the actual pharmacy…at that time of being vulnerable, I just wanted it to be at home, just delivered to me. Just open my door, get my pills, and take it." (20 yo, Louisiana)**

Recommendations for implementing misoprostol-only in the United States

Researchers conducted interviews with clinicians, clinic administrators, clinic staff, and advocates in the United States who provide or work on the topic of medication abortion. We asked what resources and tools would be needed to implement a misoprostol-only regimen in the clinic setting. These included:

- Clear and thorough patient education materials focused on effectiveness, side effects, and cost
- Counseling guidelines
- Standard misoprostol-only protocol
- Strategies for shifts in clinic flow or follow-up care, if necessary
- Research to document patient experiences with misoprostol only, particularly among those who may be more likely to choose it because of cost
- Provider testimonials, speaking about their experience, their fears, and their suggestions

> **"It's all about how you talk about it with your patients, so developing the appropriate patient-education and consent materials so that people really understand the differences and the possibilities of outcomes and so that we are not making the choice for the patient."**

> **"People need more visuals of what to expect, less sanitized versions of what's going to happen, with a broader range of expected outcome."**

> **"[We] would want to hear what patients who did it felt like. [We don't] want people miserable. It's not like we want to prohibit access. It's like we just don't want people to come away from our clinic having had a bad experience."**

Conclusion

Misoprostol-only has continued to be widely used around the world for abortion, particularly in legally restrictive contexts or where mifepristone is not registered. Misoprostol is low cost, shelf stable, easy to administer, and has a wide range of indications, making it easily accessible in many contexts. Misoprostol-only regimens can also open opportunities for innovative access via nontraditional providers and pharmacists, among others. As abortion access—and specifically medication abortion—comes under increasing legal attack in the United States and around the world, expanding the availability of existing, evidence-based methods for medication abortion can help to ensure that all people can access abortion when and where they need it.

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